Applicant: Michael L. Camilleri et al Attorney's Docket No.: 07039-355001

Serial No.: 10/058,630 Filed: January 28, 2002

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## Amendments to the Claims:

This listing of claims replaces all prior versions and listings of claims in the application:

<u>Listing of Claims</u>:

- 1. (Currently amended) A method for predicting the patient responsiveness of a patient having diarrhea-IBS responsiveness to a 5-HT3 receptor antagonist alosetron, said method comprising:
  - (a) determining a genotype of the promoter region of said patient's serotonin transporter protein gene, said genotype selected from the group consisting of a long variant/long variant, short variant/long variant, and short variant/short variant; and
  - (b) correlating said long variant/long variant genotype with <u>a</u> greater patient responsiveness to <u>alosetron</u> said 5-HT3 receptor antagonist as compared to the responsiveness to <u>alosetron said 5-HT3 receptor antagonist</u> of a patient having said short variant/long variant genotype or said short variant/short variant genotype.
  - 2. 4. (Cancelled).
- 5. (Previously presented) The method of claim 1, wherein said genotyping step comprises:
  - (a) amplifying a nucleic acid comprising the promoter region of said patient's serotonin transporter protein gene to obtain an amplified product; and
  - (b) determining the size of said amplified product to identify the long variant/long variant, short variant/long variant, or short variant/short variant genotype of the promoter region of said patient's serotonin transporter protein gene.
  - 6. 7. (Cancelled).

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8. (Previously presented) The method of claim 1, wherein said greater patient responsiveness is determined by measuring a patient parameter.

- 9. (Previously presented) The method of claim 1, wherein said greater patient responsiveness is determined by comparing a measured patient parameter with a pre-determined clinically significant threshold.
- 10. (Currently amended) The method of claim 9, wherein said measured patient parameter is a net negative change in a geometric center of colonic transit after treatment with said alosetron 5-HT3 receptor antagonist.
- 11. (Original) The method of claim 9, wherein said pre-determined clinically significant threshold is a net negative change in the geometric center of colonic transit of at least about 1.14 colonic regions.
- 12. (Currently amended) A method for treating a patient with diarrhea-predominant irritable bowel syndrome comprising:
  - (a) providing a biological sample from said patient;
  - (b) genotyping the promoter region of the serotonin transporter protein gene in said biological sample obtained from said patient; and
  - (c) administering to said patient an effective amount of <u>alosetron</u> a 5-HT3 receptor antagonist after determining that said patient has a long variant/long variant genotype in the promoter region of the serotonin transporter protein gene.
- 13. (Original) The method of claim 12, wherein said biological sample is selected from the group consisting of a blood and a tissue sample.

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14. (Currently amended) A method for identifying a <u>diarrhea-IBS</u> patient population for inclusion in an <u>alosetron</u> 5-HT3 receptor antagonist clinical trial comprising:

- (a) obtaining a biological sample from a potential participant in said clinical trial;
- (b) genotyping the promoter region of the serotonin transporter protein gene contained within said biological sample; and
- (c) identifying said potential participant as suitable for inclusion in said patient population based on the presence of a long variant/long variant genotype in the promoter region of said potential participant's serotonin transporter protein gene.